

REMARKS

In response to the Notice of Non-Compliant Amendment, Applicant has deleted the text of all canceled claims. The new listing of claims includes no new matter.

For the Examiner's convenience, Applicants have included the remarks made in the amendment of July 16, 2008, below:

The Applicants respectfully request entry of the amendments set forth above and reconsideration and withdrawal of the restriction requirement, objections, and the claim rejections in view of the amendments and the following remarks.

Applicants have amended claims 123, 124, 125, 127, 128, 144, 145, 150, and 157-162 to correct typographic and/or grammatical errors, to improve form, and/or to further clarify the subject matter claimed and have added claim 163. Support for these amendments can be found throughout the specification, including in the original claims. No new matter is introduced.

Withdrawal of Previous Rejections

Applicants acknowledge and thank the Examiner for the withdrawal of all objections and rejections not expressly set forth in the Office Action.

Restriction Requirement

Applicants maintain their traversal of the restriction requirement for at least the reasons forth in previous Office Action responses and respectfully request reconsideration and withdrawal of the restriction requirement.

Rejections under 35 U.S.C. 112, second paragraph

Claims 121-135, 137-140, 144-145, and 157-161 are rejected under 35 USC 112, second paragraph, as allegedly being indefinite for reasons detailed in the Office Action. In the interests of advancing prosecution and without waiver or disclaimer, Applicants have amended the claims as described below:

Applicants have amended claims 124 and 127 as suggested by the Examiner to recite a substituted amino acid at the indicated position. Withdrawal of the rejection of claims 124 and 127 is respectfully requested.

Applicants have amended claims 125 and 128 to recite that the claimed SCHAG amino acid sequence has exactly one amino acid with a reactive side chain. Applicants note that claim 124 recites a purified polypeptide comprising a SCHAG amino acid sequence that is *at least 90% identical* to amino acids 2 to 113 of SEQ ID NO: 2 and claim 127 recites a purified polypeptide comprising a SCHAG amino acid sequence that is *at least 90% identical* to amino acids 2 to 253 of SEQ ID NO: 2 (emphasis added). The claimed polypeptides are therefore not limited to one substitution of one amino acid within SEQ ID NO: 2 since 90% identity as recited in the claims would encompass polypeptides having more than a single substitution.

Claims 144 and 145 have been amended to remove the recitation of “or comprising a fragment thereof...”, thereby obviating the rejection.

Claim 157 and other claims dependent on claim 155 have been amended to replace “fiber” with “polypeptide” thereby providing antecedent basis.

In view of the amendments and comments above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 USC 112, second paragraph.

Rejections under 35 U.S.C. 112, first paragraph

Claims 121-123, 139-140, 144-145, 150-155 and 157-161 remain rejected under 35 U.S.C. 112 as allegedly failing to comply with the written description requirement for reasons of record in the office action of May 24, 2007. Applicants respectfully disagree with the Examiner for at least the reasons set forth in the Office Action Response filed Oct. 31, 2007. Applicants respectfully disagree with the Examiner’s characterization of at least some of the claimed polypeptides as having no structural similarity with SEQ ID NO: 2 (Office Action, p. 6, line 10). Applicants also respectfully disagree with the Examiner’s application to the instant invention of case law developed in the context of claims to naturally occurring nucleic acid and/or protein sequences, in which the proteins have specific biological activities based on receptor-ligand interactions and/or in which the claim is to specific sequences as found in particular organisms (e.g., “human insulin cDNA” as in *Lilly*). Nonetheless, solely in order to advance prosecution and without waiver, disclaimer, or prejudice, Applicants have amended the claims as follows:

Claims 144, 145, and 150 have been amended to remove the recitation of fragments and, in the case of claim 150, the recitation of variants. Claims 144 and 145 as amended recite “a sequence at least 90% identical to the SCHAG amino acid sequence of SEQ ID NO: 2”, with the proviso that the amino acid at position 2 (claim 144) or 184 (claim 145) is occupied by particular amino acid(s) recited in the claims. Claim 150, as amended, recites “amino acid sequences that are at least 90% (a) or (b) and that self-coalesce into ordered aggregates”, where (a) is “amino acids 2-253 of SEQ ID NO: 2”; and (b) is “amino acids 2-113 of SEQ ID NO: 2”. Applicants respectfully submit that claims 144, 145, and 150, as amended, are consistent with claims 124 and 127 as examined in the Office Action, which also recite “at least 90% identical” and were not rejected for alleged lack of written description. Applicants respectfully submit claims 121-123, 139-140, 151-155 and 157-161 all depend on claim 144, 145, or 150 and thus also include a limitation of at least 90% identity. In view of the amendments and comments above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 112.

Rejections under 35 U.S.C. 103

Claims 150 and 151 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Kushnirov, et al., 1988 (Gene, 66, pp. 45-54). The Examiner asserts that the claims encompass full length Sup35 with a label attached and that it would have been obvious to conjugate the polypeptide with various labels “for purposes of protein identification”. Applicants respectfully disagree for each of the following reasons.

First, Applicants respectfully submit that the Examiner has not met the burden of establishing a *prima facie* case of obviousness. As described in MPEP 2143 and consistent with the Supreme Court’s decision in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395-97 (2007), the “key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.” Applicants respectfully submit that the Examiner has not clearly indicated what is intended by the term “protein identification” or how labeling Sup35 would be of use for “protein

identification”. If the term “protein identification” means “determining the identity of the protein”, Applicants respectfully submit that it is not clear how labeling the protein would achieve such purpose. Should the Examiner maintain the rejection, clarification is respectfully requested.

Second, Applicants respectfully submit that claim 150 as previously presented recites that the substituent is attached *to a side chain* of the SCHAG polypeptide (emphasis added), not simply to the SCHAG polypeptide. The Examiner has not set forth any evidence or reasoning to support a conclusion that it would have been obvious to attach a substituent to a side chain of the SCHAG polypeptide, as recited in the claim, or that the art of attaching substituents to side chains of polypeptides is “old and well-known”. Applicants respectfully submit that, even if it would have been obvious to label Sup35 based on the teachings of Kushnirov, which Applicants do not concede, it would not have been obvious to attach the label to a side chain of the SCHAG polypeptide rather than elsewhere, e.g., at the N- or C-terminus of the polypeptide.

Third, Applicants respectfully submit that, given that Kushnirov was published in 1988, if it would have been obvious to label Sup35 by attaching a label to a side chain, those of skill in the art would have done so in the more than 10 years that elapsed between Kushnirov’s publication and the filing of the instant application. The apparent dearth in the literature of examples of labeling Sup35, let alone labeling Sup35 by attaching a label to a side chain, argues that it would not have been obvious to the skilled artisan to do so.

Fourth, Applicants submit that the rejection is rendered moot by the instant amendment to claim 150 to recite that the side chain is one that is exposed to the environment when the SCHAG polypeptide self-coalesces to form an ordered aggregate. Support for the amendment and for new claim 163 is found, e.g., at p. 23, line 25 – p. 28, line 2. Recognition of the utility of attaching substituents to side chains of SCHAG amino acid sequences that are exposed to the environment when the SCHAG polypeptide self-coalesces, and methods of identifying such side chains, are aspects of the instant application. Applicants submit that, prior to the instant invention, the art did not teach or suggest the possibility or the utility of

attaching substituents to side chains of SCHAG amino acid sequences that are exposed to the environment when the SCHAG polypeptide self-coalesces and did not teach or suggest methods of identifying such side chains in SCHAG polypeptides or attaching substituents thereto.

In view of the amendments and comments above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a).

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Respectfully submitted,

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